

FEB 1 2 2002

**10.0 510 (k) SUMMARY****10.1 Submitter's Name**

Francis X. Hursey,  
President

**10.2 Address**

On Site Gas Systems. Inc.  
35 Budney Road  
Budney Industrial Park  
Newington, CT 06111

**10.3 Phone**

888-748-3429 (Toll-free)  
860-667-8888

**10.4 Fax**

860-667-2222

**10.5 Contact Person**

C. Barton ("Bart") Gullong,  
Vice President,  
Marketing and Technical Services

**10.6 Date of Preparation**

January 28, 2002

**10.7 Device Name**

Portable Oxygen Generator

**10.8 Trade Name**

On Site Gas Systems Portable Oxygen Generation System

**10.9 Common Name**

Oxygen Concentrator

**10.10 Proprietary Name**

P.O.G.S. - 3.3

**10.11 Classification Name**

Portable Oxygen Generator

**10.12 Legally Marketed Device Claiming Substantial  
Equivalency To:**

K 014078 On Site Gas Systems Portable Oxygen Generation System  
K 011844 Merits Health Products Oxygen Concentrators  
K 955549 Oxlife Oxygen Concentrators

**10.13 Description of the Device**

The On Site Gas Systems portable oxygen generator is a prescription device designed to provide an inexpensive supply of supplemental oxygen in a military environment without a continuous source of oxygen. The feed air compressor creates a vacuum to draw air into a holding tank. The air is then flushed through two tanks in series to provide continuous oxygen. The molecular sieve material adsorbs nitrogen, which comprises approximately 78% of the makeup of air. The resulting gas is approximately 93% oxygen.

The variations of the device are to allow for greater total flow, to accommodate more cannulas per device. The variations are designed and tested for same indication of use, safety and effectiveness; variations are substantially equivalent to predicate devices.

**10.14 Intended Use of Device**

The POGS is intended to provide supplemental oxygen. Device is to be operated by trained medical personnel for military use only.

**10.15 Summary of Technological Characteristics of Device  
Compared to Predicates**

The oxygen generator operates by using molecular sieve material to adsorb the nitrogen from filtered air. The resulting gas has an increased concentration of oxygen. This technology is well established, and has been used in the predicate device as well as other legally marketed products.

#### **10.16 Discussion of Non-clinical Test to Support Determination of Substantial Equivalency**

#### **10.17 Performance Data**

The device meets the requirements of the FDA recognized standard covering Oxygen Concentrators, ASTM F 1464-93, and is substantially equivalent to the predicate devices.

#### **10.18 Conclusions**

Based on the design, performance specifications, and intended use, the Oxygen Concentrators are substantially equivalent to the currently marketed devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**FEB 12 2002**

Mr. C. Barton Gullong  
On Site Gas Systems Inc.  
35 Budney Road  
Budney Park Industrial  
Newington, CT 06111

Re: K020362  
P.O.G.S. 3.3 Portable Oxygen Generator System  
Regulation Number: 868.5440  
Regulation Name: Generator, Oxygen, Portable  
Regulatory Class: Class II (two)  
Product Code: 73 CAW  
Dated: January 28, 2002  
Received: February 4, 2002

Dear Mr. Gullong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

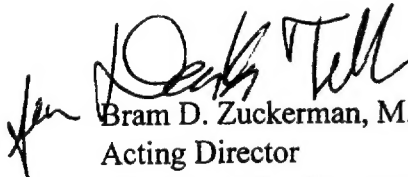
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
Bram D. Zuckerman, M.D.  
Acting Director  
Division of Cardiovascular  
and Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

# **O<sub>2</sub>N<sub>2</sub> SITE**

## **On Site Gas Systems, Inc.**

Manufacturers / Designers of Oxygen & Nitrogen Generating Equipment

### **8.10 Statement of Indications for Use**

#### **8.10.1 510 (k) File Number**


K020362


#### **8.10.2 Device Name**

On Site Gas Systems  
Portable Oxygen Generation System - 3.3

#### **8.10.3 Indications for Use**

The POGS is intended to provide supplemental oxygen. Device is to be operated by trained medical personnel only for military use only.

Prescription Use   
(Per 21 CFR 801.109)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K020362

### **On Site Gas Systems, Inc.**

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